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SUPERINDUSTRIA Y COMERCIO

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Tramite : 011 PCT-PATENT 332 PRESENTAC 329 COMPLEME

Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

E. _____ S. _____ D. _____

Re: P1.-**SOCIETE DES PRODUITS NESTLÉ S.A.**-Expediente
número **02-117.313.-**

1. Me refiero al memorial de sustitución de poder presentado a ese Despacho el 30 de Agosto de 2004.

2. Por medio del presente, atentamente me permito manifestar a ese Despacho, que hubo un **cambio** de Representante Legal para todos los asuntos de la Propiedad Industrial en Bogotá de **SOCIETE DES PRODUITS NESTLÉ S.A.**, una sociedad organizada y existente de conformidad con las leyes de Suiza, domiciliada en Vevey, Suiza.

3. En consecuencia, atentamente solicito a ese Despacho reconocerme personería, en este asunto, de conformidad con el documento de Representación Legal para todos los asuntos de la Propiedad Industrial en Bogotá de la sociedad **SOCIETE DES PRODUITS NESTLÉ S.A.**, otorgado a favor del **SUSCRITO (GUSTAVO TAMAYO)** y/o a la doctora ALICIA LLOREDA y/o al doctor IGNACIO SANTAMARIA y/o al doctor ENRIQUE ALVAREZ de acuerdo con la copia debidamente autenticada ante Notario Público que adjunto al presente expediente (Artículos 26 y 39 de la Decisión 486 de la Comunidad Andina de Naciones).

4. Anexo al presente acompaño fotocopia, de:

- (a) Documento que acredita al SUSCRITO y/o a la doctora ALICIA LLOREDA y/o al doctor IGNACIO SANTAMARIA y/o al doctor ENRIQUE ALVAREZ en los términos del parágrafo 1º. del Artículo 543 del Decreto-Ley 410 de 1971, como Representantes Legales en Bogotá para todos los asuntos relacionados con la propiedad industrial de la sociedad **SOCIETE DES PRODUITS NESTLÉ S.A.**, una sociedad organizada y existente de conformidad con las leyes de Suiza, domiciliada en Vevey, Suiza;

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(b) Certificación Notarial expedida el 11 de Agosto de 2004; y

(c) Traducción Oficial No. 284/04 correspondiente a las partes pertinentes del documento anterior, también debidamente legalizada hasta por el Ministerio de Relaciones Exteriores bajo el número 061225 de 2 de Septiembre de 2004.

5. Finalmente, llamo la atención de ese Despacho al hecho de que la copia auténtica del documento que me acredita para actuar como Representante Legal de la sociedad peticionaria, reposa en el Expediente número **98-034.405**.

6. Ruego a usted tomar atenta nota de lo anterior y continuar con el trámite correspondiente.

Señor Superintendente,


GUSTAVO TAMAYO

T.P. 37.172

Código 231

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TRADUCCIÓN OFICIAL No.284/04 DE UN DOCUMENTO ESCRITO EN FRANCÉS, EL CUAL PARA SU IDENTIFICACIÓN SE SELLA CON EL SELLO DEL TRADUCTOR. ESTA ES UNA TRADUCCIÓN OFICIAL EFECTUADA EL DIA 01 DE SEPTIEMBRE DE 2004 POR JEAN-JACQUES TURPIN, C.E.: 193849 DE BOGOTÁ, TRADUCTOR E INTÉRPRETE OFICIAL SEGÚN RESOLUCIÓN No. 2680/91 DEL 19 DE DICIEMBRE DE 1991, EXPEDIDA POR EL MINISTERIO DE JUSTICIA DE COLOMBIA.

Autenticaciones que se hallan a continuación de un documento de poder conferido en inglés y español por **SOCIÉTÉ DES PRODUITS NESTLE S.A.**, una sociedad organizada y existe de conformidad con las leyes de Suiza, domiciliada en Vevey, Suiza, y otorgado a los Doctores ALICIA LLOREDA y/o GUSTAVO TAMAYO y/o IGNACIO SANTAMARÍA y/o ENRIQUE ÁLVAREZ, todos domiciliados en Bogotá, Colombia, Calle 72 No. 5 – 83 (Piso 6°).

Dado el 5 de agosto de 2004. Firma ilegible de la Señora Paula Nelson, con firma autorizada.

CERTIFICADO NOTARIAL (SOCIEDAD)

Legalización por parte del suscrito Notario de la firma de la Señora **Paula NELSON** quien desempeña el cargo de (en blanco) de la compañía **SOCIÉTÉ DES PRODUITS NESTLE S.A.**, una sociedad legalmente constituida y existente de acuerdo con las leyes de **Suiza**, domiciliada en **Vevey (Suiza)**. Además, dicho Notario certifica que el signatario, según las leyes de **Suiza**, tiene facultad para otorgar el presente documento. Los hechos anteriores le constan por haber examinado los documentos respectivos el 13 de junio de 1997, y de todo ello da fe.

Firma de Jean-Daniel RUMPF. Sello: Jean-Daniel RUMPF – Notario.

284/04

Traducción Oficial No.
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCOIS - ESPANOL
Res. Minjusticia No. 2680/91

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Legalización No. 7.136. El Notario Jean-Daniel RUMPF, en Vevey, Distrito de Vevey, Cantón de Vaud, Suiza, certifica la firma puesta en la página anterior por la Señora Paula Nelson, quien compromete en forma válida con su firma individual a la SOCIÉTÉ DES PRODUITS NESTLE S.A. en Vevey.

Dado en Vevey, el once de agosto de dos mil cuatro. Firma ilegible del Notario.

Sello: Jean-Daniel RUMPF – Notario. Estampilla de 4 Frs.

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

1. - País: Suiza

El presente documento público

2. - ha sido firmado por el Señor Jean-Daniel RUMPF

3. - obrando en calidad de Notario en Vevey

4. - con sello de Jean-Daniel RUMPF, Notario

CERTIFICADO

5. - En Lausana

6.- El 12 de agosto de 2004

7. - Por la Cancillería de Estado del Cantón de Vaud

8. - Bajo el número 6706

9. - Sello: Cancillería del Consejo de Estado – Libertad y Patria - Emolumento de 25 Fr.

10. - Por el Canciller de Estado, firma de P. Equey.

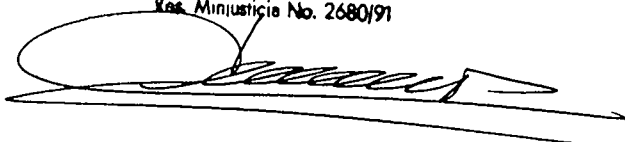
Es traducción fiel y completa de la cual se deja copia en los archivos de esta oficina para confrontación y a la cual me remito.

Traducción oficial No. 284/04.

Traductor: Jean-Jacques Turpin.

Bogotá, D.C., 1 de septiembre de 2004.

Traducción Oficial No. 284/04
JEAN - JACQUES H. TURPIN
Traductor e Intérprete Oficial
FRANCOIS - ESPANOL
Res. Minjusticia No. 2680/91



Los abajo firmados, **SOCIETE DES PRODUITS NESTLE S.A.**, una sociedad organizada y existente de conformidad con las leyes de Suiza

con domicilio en **Vevey, Suiza**

The undersigned, **SOCIETE DES PRODUITS NESTLE S.A.**, a corporation organized and existing under the laws of Switzerland.

domiciled at **Vevey, Switzerland**

nombramos por el presente a ALICIA LLOREDA y/o GUSTAVO TAMAYO y/o IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ, domiciliados en Bogotá, Colombia, con oficinas en dicha ciudad, Calle 72 No. 5-83, piso 6o., nuestros representantes legales y verdaderos en Bogotá, con facultades para recibir notificaciones y nombrar apoderados judiciales o extrajudiciales, con el fin de dar cumplimiento al parágrafo 1o. del artículo 543 del decreto 410 de 1971.

Los doctores ALICIA LLOREDA y/o GUSTAVO TAMAYO y/o IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ, o los apoderados que cualquiera de ellos designe, quedan especialmente facultados para representarnos ante las autoridades colombianas, administrativas, judiciales o de policía, en todos los trámites relativos a la propiedad industrial, a cuyo efecto les facultamos para dar ante dichas autoridades todos los pasos necesarios al objeto indicado; elevar solicitudes, declaraciones, reclamos, recursos y presentar desistimientos; formular descripciones, enmiendas, limitar el alcance de las solicitudes, presentar oposiciones y apelaciones; instaurar cancelaciones, renunciar total o parcialmente a los registros, abonar todos los impuestos y cuotas y efectuar todo otro pago determinado por la ley; recibir todos los documentos y valores, dando el descargo respectivo; llenar cualesquiera otros requisitos y tomar, en fin, todas las medidas que creyeran conducentes al resguardo de nuestros intereses; y en caso de producirse oposición, pasando los antecedentes a los tribunales, quedan facultados para tomar intervención como demandantes o demandados ante los jueces que sean competentes, pudiendo transar, someter a árbitros, desistir, percibir y apelar, con todas las demás facultades que resulten necesarias, y por el presente declaramos desde ahora válido y bueno cuanto dichos representantes y/o los apoderados que cualquiera de ellos nombre hicieren en nuestro beneficio.

Asimismo, facultamos a los doctores ALICIA LLOREDA y/o GUSTAVO TAMAYO y/o IGNACIO SANTAMARIA y/o ENRIQUE ALVAREZ, para solicitar en la Oficina de Propiedad Industrial la protocolización de este documento y de cualquier poder que cualquiera de ellos otorgue a nombre nuestro.

Dado y firmado

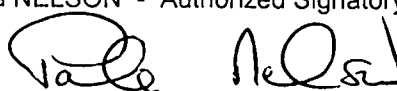
hereby appoint, ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, of Bogota, Colombia, with offices in said town, Calle 72 No. 5-83, Sixth Floor, our true and legal representatives in Bogotá, with power to receive notifications and to appoint judicial or extrajudicial agents, so as to comply with paragraph 1o. of article 543 of decree 410 of 1971.

Doctors ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, or the agents by any one of them appointed, are especially empowered to represent us before the administrative, judicial or police authorities of Colombia, in all proceedings pertaining to industrial property, for which purpose we authorize them to take before the said authorities all the necessary steps for the said end; to file petitions, declarations, claims, recourses and withdrawals, to draw up specifications; to file amendments, to limit the scope of applications, file oppositions; file cancellations total or partially waive registrations, to pay all installments and effect all other payments prescribed by law; to receive proper receipts, to comply with all other requirements and, in short, to take all those measures which they may deem fit for the protection of our interests; and in case of opposition, where the proceedings be passed over to the courts, we authorize said agents to act on our behalf, as complainants as well as defendants, before the competent judges, with full powers to make arrangements, to submit to arbitrators, to desist, to collect, to appeal and, in short, with all such further powers as may be required, and we hereby declare from now on as valid and good all that said representatives and/or the agents by any one of them appointed may do for our benefit.

We also authorize doctors ALICIA LLOREDA and/or GUSTAVO TAMAYO and/or IGNACIO SANTAMARIA and/or ENRIQUE ALVAREZ, to apply for protocolization of this document and of any power of attorney by any one of them conferred in our name, before the Office of Industrial Property.

Given and signed this (date): 5th August 2004

Paula NELSON - Authorized Signatory



NOTARY SHOULD EXECUTE OTHER SIDE

CERTIFICADO NOTARIAL (SOCIEDAD)

Suiza
Vevey {ss

Hoy 11 de Agosto de 2004
compareció PAULA NELSON, a quien conozco y
de quien me consta que firmó el anterior documento,
y quien debidamente juramentado declaró y dijo que
él es la persona autorizada por sus-
cribir documentos de SOCIETE DES
PRODUITS NESTLE S.A., la compañía nombrada en
el documento que antecede, una sociedad
debidamente organizada y existente conforme a las
leyes de Suiza, domiciliada en la ciudad de
Vevey, Suiza legalmente constituida para un período
de duración que aún no ha terminado, que ejerce su
objeto social; conforme a las leyes de Suiza, que el
declarante está autorizado por dicha Compañía para
conferir este poder; que el sello estampado por él al
pie de tal poder, en nombre y en representación de la
expresada Compañía, es el sello oficial de ella; y que
el objeto para el cual se confiere este instrumento
está comprendido dentro del de la sociedad.
El suscrito Notario ha visto los Estatutos de
incorporación firmados en Vevey, Suiza, con fecha
Noviembre 27, 1936, y certifica que de conformidad
con la legislación de dicho País, la anterior
declaración juramentada es prueba suficiente de que
los hechos sobre que ella versa son ciertos o
verdaderos, de lo cual da fe.

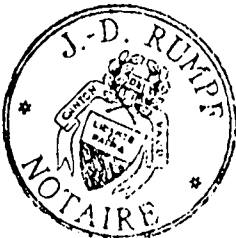
NOTARIAL CERTIFICATE (CORPORATION)

Switzerland
Vevey {ss

On this 11th day of August 2004,
personally came Paula NELSON

to me known, and known to me to be the person who
signed the foregoing instrument, who being by me
duly sworn did depose and say that he/she is the
Authorized Signatory of SOCIETE DES PRODUITS
NESTLE S.A., the company named within, a
Corporation organized and existing under the laws of
the Switzerland, domiciled at the City of Vevey,
Switzerland legally constituted for a period of tenure
not yet expired, which exercises its corporate
purposes according to the laws of Switzerland, that
the deponent is authorized by said Company to
confer this power of attorney; that the seal affixed
hereunto by the deponent in the name and on behalf
of said Corporation is the corporate seal thereof; and
that the purpose for which this instrument is granted
is included within the corporate purposes of the
Company.
The undersigned Notary Public has seen the articles
of Incorporation of said Corporation executed at
Vevey, Switzerland, under date of November 27,
1936, and hereby certifies that under the laws of said
County the foregoing acknowledgment is sufficient
proof that the facts therein contained are true, which
he attests. 1 June 13, 1997

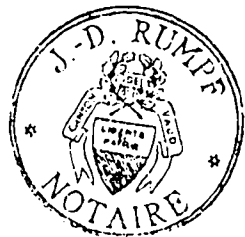
Notary Public (Notario Público).



J.D. Rumpf

Légalisation No 7'136.-

Le notaire JEAN-DANIEL RUMPF, à Vevey, District de Vevey, Canton de
Vaud, Suisse, certifie authentique la signature apposée d'autre ---
part par Mme Paula NELSON, laquelle engage valablement la SOCIETE -
DES PRODUITS NESTLE SA, à Vevey, par sa signature individuelle. ----
VEVEY, LE ONZE AOÛT DEUX MILLE QUATRE. -----



J.D. Rumpf

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Pays: SUISSE

Le présent acte public

2. a été signé par Jean-Daniel Rumpf

3. agissant en qualité de notaire à Vevey

4. est revêtu du sceau/timbre de J.-D. Rumpf notaire

Attesté

5. à Lausanne 6. le 12 août 2004

7. par la Chancellerie d'Etat du Canton de Vaud

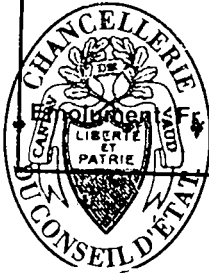
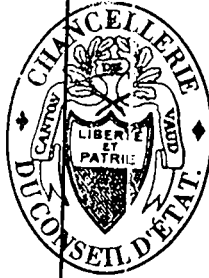
8. sous No 6706

9. Sceau/timbre:

10. Signature
pr le Chancelier d'Etat:



P.Equey



25.-

DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 02- 117313

**EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION -
PCT, FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 531,
DE FECHA 29 DE AGOSTO DE 2003, EL TERMINO HABIL SEÑALADO POR LA
LEY EXPIRA EL 29 DE NOVIEMBRE DE 2003.**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI

NO **X**



US005525352A

United States Patent [19]

Kontos et al.

[11] Patent Number: 5,525,352

[45] Date of Patent: Jun. 11, 1996

[54] CONFECTIONERY DELIVERY SYSTEM FOR PHARMACEUTICALLY ACTIVE SUBSTANCES

[76] Inventors: Angelos Kontos; Georgios C. Kontos, both of 4 Kerkyras Street, GR-146 71 Kastri, Greece

[21] Appl. No.: 244,817

[22] PCT Filed: Oct. 18, 1993

[86] PCT No.: PCT/GR93/00018

§ 371 Date: Jun. 28, 1994

§ 102(e) Date: Jun. 28, 1994

[87] PCT Pub. No.: WO94/09758

PCT Pub. Date: May 11, 1994

[30] Foreign Application Priority Data

Nov. 5, 1992 [GR] Greece 920100490

[51] Int. Cl.⁶ A61K 9/20

[52] U.S. Cl. 424/440; 424/486

[58] Field of Search 424/440, 441, 424/457, 468, 490; 426/101, 103, 66-68, 139, 312, 303, 565, 654, 558, 524, 660-662

[56] References Cited

U.S. PATENT DOCUMENTS

4,086,370	4/1978	Olds et al.	426/101
4,104,405	8/1978	Forkner	426/101
4,104,411	8/1978	Poaler	426/100
4,127,679	11/1978	Amano et al.	426/565
4,725,445	2/1988	Ferrero	426/565
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4,785,833	11/1988	Holzner et al.	131/310
4,853,246	8/1989	Stevens	426/580
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5,135,767	8/1992	Daouse	426/515
5,343,710	9/1994	Cathenaut et al.	426/100

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Derwent Publications Ltd., London, GB; AN 90-035088, Database WPI, Week 9005 & SE, A, 8 800 634 (Semper AB) 25 Aug. 1989.

Derwent Publications Ltd., London, GB; AN 85-185973, Database WPI, Week 8531, & JP, A, 60 112 720 (Kosaka) 19 Jun. 1985.

Derwent Publications Ltd., London, GB; AN 90-120673, Database WPI, Week 9016, & JP, A, 2 072 121 (Yakult Honsha KK et al.) 12 Mar. 1990.

Primary Examiner—Thurman K. Page
Attorney, Agent, or Firm—Ladas & Parry

[57] ABSTRACT

The invention relates to a confectionery form of matrix suited to contain microcapsules for controlled release of pharmaceutically active substances, of fixed content, which is soluble in the mouth and readily swallowed without chewing, as well as the process for the preparation thereof. In a preferred embodiment, the confectionery matrix is ice cream and a confectionery formulation is prepared by mixing he microcapsules with the ice cream in a liquid phase and then solidifying the mixture. The microcapsules are coated with a water-proof substance to protect the pharmaceutically active substances from eutectic water.

22 Claims, No Drawings

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**CONFECTIONERY DELIVERY SYSTEM FOR
PHARMACEUTICALLY ACTIVE
SUBSTANCES**

The aim of the present invention is to propose a confectionery form of matrix suited to contain microcapsules for controlled release of pharmacologically active substances, of fixed content, which is soluble in the mouth and readily swallowed without chewing, as well as the process for the preparation thereof.

Since the microcapsules for controlled release of pharmacologically active substances are not resistant to the high pressures created in the tableting machines, tablets containing microcapsules for controlled release of pharmaceutically active substances are rarely manufactured.

Thus, the most widespread form for the oral administration of microcapsules for controlled release of pharmaceutically active substances are the gelatin capsules.

However, many patients and particularly children refuse to swallow a medicine in the form of a usual gelatin capsule available in the market.

In these patients, the feeling that the capsule is a foreign body that may make them choke neutralizes the mechanism of swallowing.

The need consequently exists for the creation of a system of a matrix that would permit the easy oral administration of microcapsules for controlled release of pharmaceutically active substances, which is soluble in the mouth without chewing.

PRIOR STATE-OF-THE-ART

DE-A 336 216 describes a process for coating pharmaceutically active substances for the formation of microcapsules which are resistant to the pressures created during tableting, nevertheless, it imposes considerable limitations in the selection of materials used for said coating.

FR-A 2011960 renders formulated pieces which include microcapsules containing pharmaceutically active substances administered orally, nevertheless, it presents the disadvantage that the mixture to be formulated is exposed to relatively high temperatures for considerable time, a fact which creates serious risks for alteration or for shortening of the shelf-life of various thermolabile pharmaceutical substances.

Patent Application EP-0 239983 describes a process which avoids the high temperatures employed in FR-A 2011960 but which, despite the fact that it makes use of readily melted mixtures, likewise strains, from the thermal point of view, even though to a smaller extent, the pharmaceutically active substances.

Patent Application EP-0 227603 grants a confectionery system for the administration of medicines by means of chewing but likewise strains, from the thermal point of view, the protected pharmaceutically active substances.

EP-A 0267160 describes a product which is likewise thermically strained in the course of its processing.

DESCRIPTION OF THE INVENTION

In accordance with the present invention, the aforementioned problem is solved by addition of the aforementioned known per se microcapsules for controlled release of pharmaceutically active substances (see for instance

- 1) Remington's Pharmaceutical Sciences Handbook, Mack, Publ. Co. New York U.S.A. 18th Edition Pages 1663-1665

- 2) M. Riag, N. Weiner, F. Martin in H. Lieberman, N. Prueger, G. Banker Eds.: *Pharmaceutical Dosage Forms—Disperse Systems*, Vol. 2
- 3) Jones D. M., Factors for consideration in fluid bed processing. *Pharmaceutical Technology*, April 1985
- 4) Ebert W. R., *Pharm. Tech.* I (10): 44, 1977
- 5) Madan P. L., *Pharm. Tech.* I (10): 68, 1978
- 6) Jager K. F. et al. "Effort of Material Motion on Agglomeration in the Rotary Fluidized-Bed Granulator" *Drug Made in Germany*, Vol. XXV pp. 61-65 (1982), incorporated to the present description by reference)

into a suitable low viscosity, fluid confectionery cream system of ice cream substitute under stirring, at a temperature ranging between -1° C. and 0° C., and its immediate feeding into a device of continuous or non-continuous operation, for production and kneading of ice cream, where it is solidified, under nitrogen bubbling, under pressure, in a matrix for enclosure of microcapsules and it is formulated, preferably, in cup-shaped pieces or in ice cream borne on a small wooden rod, in certain cases of bulky pharmaceuticals, such as for instance in the case of cathartic plant fibers or of nutritive elements, which are administered in large single doses of up to approximately 100 grams, or in the shape of geometrical or artistic shape, or color, confectionery preparations of this sort, of low weight and of small dimensions, for all medicinal products that are usually administered each time in quantities below one gram, at a final temperature of -18° C. It is evident to those skilled in the art that, when, in certain cases, it is necessary to effect an even better homogenizing of the microcapsules within the confectionery matrix, the formulated product may be recycled to the kneading department of the facility and subjected, once again, to the production process.

Furthermore, it is obvious that provision may be made, in the facilities for production and kneading of the ice cream, to have the scrapers of the cooling surfaces shorter and bearing soft elastic extremities on their edges, in order to avoid the creation of high pressures between the metal surface, which could eventually bring about the destruction of the coatings of the microcapsules. Of course, during the blowing of the nitrogen, the maintenance of the highest possible temperatures ensures, in the best possible manner, the protection of the coatings of the microcapsules.

Nevertheless, even at the temperature of -18° C., there still exists, within the solid confectionery matrix that is so formed, a small quantity of water (A. W. Farall, *Engineering for Dairy and Food Products*, page 300) which contains dissolved amounts of sugar, glucose, milk salts, etc. and which has not solidified. In the long run, this constitutes a risk in keeping intact the totality of the microcapsules containing the active substance of the cathartic plant fibers etc.

The inventors have also solved the aforementioned problem in the following manner. The capsules and the water soluble plant fibers are rendered provisionally water-proof, at low temperatures below zero, before their addition to the binding confectionery mixture which creates the matrix that consists of the principle solid phase of the ice cream, the possibly minimal aforementioned eutectic still liquid phase and the abundant gaseous phase of the enclosed nitrogen. The provisional water-proofing is carried out inside a rotating, inclined with respect to the vertical axis, special container designed for the coating of tablets or microcapsules (coating-drum), by coating with an adequate amount of

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edible vegetal oil, such as for instances peanut oil, sesame oil, olive oil, palm oil, etc., which is added at a very slow rate in small doses, in the form of spray produced under very large pressure, and subsequently by blowing cool air at a temperature sufficiently lower than that of the melting point of the corresponding oil, in order to obtain the polishing of the microcapsules (microspherules). The coated microcapsules are transferred immediately to the stock container, under stirring, and are added to the aforementioned cream mixture which is likewise at a temperature of approximately 0° C. to -1° C. It would be clear to those of skill in the art that the water-proof microcapsules, instead of being added in the stirred stock container of the cream of the ice cream substitute, in their totality and in a precisely fixed ratio, may be fed into a special capsule-filling machine and dispensed with dosimetric accuracy into the corresponding forming molds of the aforementioned geometrically shaped formulations between two or more superposed layers of ice-cream substitute in the form of a sandwich. Alternatively, it may be possible to use, for the polishing process, anhydrous molten cooking milk butter, working under the same conditions of cooling.

If so desired, the microcapsules may be polished prior to the aforementioned provisional water-proofing by means of a mixture of synthetic waxes, on condition that the melting point of the latter is below 30° C. It is understood that other, known clear to those of skill in the art pharmacologically accepted hydrophobic substances may also be employed for the aforementioned provisional water-proofing, at low temperatures below zero, of the confectionery matrix enclosing the microcapsules, on condition that said substances melt instantaneously at the temperature of the mouth, such as for instance liquid paraffin or mixtures thereof. The quantity of wax employed is controlled by those of skill in the art so that, in association with the amount of solidified vegetal oil, it ensures the better water-proofing of the microcapsules (spherules) containing the pharmaceutically active substance.

The weight of the vegetal oils or butter and waxes used for the water-proofing of the microcapsules ranges between 0.5% and 20% of the weight of the microencapsulated pharmaceutically active substances and preferably between 7% and 18%.

The content of the microcapsules within the confectionery matrix ranges between 0.1% and 60%, preferably between 6% and 30%, and most preferably between 8% and 20% by weight. The limits within which the contents of the various components of the aforementioned matrix of confectionery composition, which is, as far as its taste is concerned, an ice cream substitute richer or poorer in calories, may vary, are indicated below.

Water-proof microcapsules of pharmaceutically active substance	0.1-25%
milk powder FAO/WHO	1-18%
sugar USP	10-18%
lecithin USP	2-4%
casein USP	0.5-4%
vegetal gum USP	0.1-1%
synthetic sweetener USP	adequate amount
flavor USP	adequate amount
colorant USP	adequate amount
water USP, sufficient quantity up to	100%.

Without excluding the normal usage of air for the swelling (overrun) of the aforementioned ice cream substitute, the use of nitrogen or of any other inert gas is considered preferable for the better maintenance of the matrix.

In the present description, the percentage of swelling (overrun) of the ice cream is determined by the following quotient:

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liters of final volume of ice cream—liters of initial mixture
100
liters of initial mixture

The aforementioned nitrogen is introduced into the mass of the solidified and kneaded ice cream under pressure of up to 5 atmospheres from a nitrogen steel container.

The swelling (overrun) of the liquid initial confectionery mixture used may range from 30% up to 200% (volume/volume), preferably from 50% up to 150%, and is most preferably checked at 100% (volume/volume) which gives a smoother texture, in the mouth, to the cream of the ice cream which, at the temperature of the mouth, following a short stay therein, melts without having to be chewed.

The aforementioned formulated pieces may eventually be coated with one of the usual coatings such as chocolate, sugar, wafer or other from the confectionery point of view acceptable material or combination of materials, and may also bear subdividing scores. The aforementioned coating is carried out in accordance with the well known technology in the manufacture of ice cream, chocolate and caramels, in well known per se automatic machines (see for example:

- 1) Arthur W. Farall, Engineering for Dairy and Food Products, John Wiley and Sons Inc. pages 297-332, New York and London
- 2) Chocolate, Cocoa and Confectionery: Science and Technology, 2nd Edition, AVI Publishing Co. Inc., Westport, Conn. (1950)
- 3) Ice cream, 4th Edition (1986) AVI Publishing Co. Inc., which are incorporated herein by reference).

Prior to the application of the coating, the finished product that has been formulated in the proper matrix is frozen eventually below its storage temperature of approximately -20° C., at temperatures of -30° C. up to even -60° C., in order to enable even the outer surface of the ice cream that will come in contact with the possibly slightly warmer sugar-syrup or chocolate-syrup not to be subjected to any thermal strain whatsoever, not even instantaneous.

The abolition of the need for chewing brought about by this system for administration of pharmaceutically active substances eliminates the risk for application of great pressure, by the teeth, on the coatings of the active substances, which cause damage to said coatings and undesirable early release of the active substances into the mouth as well as the sense of unpleasant taste. Furthermore, it is known, from the principles of physical chemistry, that a storage temperature of the preparation of the present invention, which is 40° C. up to 80° C. lower than that of the ambient temperature, slows down by a multiple of 10⁴ up to 10⁸ approximately the rate of the reactions leading to the oxidation and the aging of the product. Furthermore, the enclosure of 100% up to 200%, by volume, of nitrogen in the preparation, in association with the favorable influence of the low temperature on the suspension of all chemical, physicochemical or microbial alteration processes, significantly lengthens the shelf life of the preparation. Besides, in accordance with Vant' Hoff's Law, a reduction of 10° C. in the temperature doubles or triples the preservation properties. It is obvious that, apart from the ice-cream composition proposed above, any composition of commercial ice cream or ice-lolly may likewise be used for the purpose of the present invention.

The aforementioned formulated pieces may also be formulated within receptors made of composite sheet with layers of paper, plastic and/or metal, and be closed hermetically. In accordance with the well known pharmacotechnical practice for manufacture of dosage forms, the dimensions and the weight of the various formulations indicated above are determined in such a manner that, depending on the

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nature and on the content of the pharmaceutically active substance contained therein, said formulations are administered once up to three times daily to cover the needs of an adult patient of body weight 70 Kg.

Pharmaceutically active substances in the form of water-proof microcapsules for controlled release, which may be used in the present invention

In the present description, the term microcapsules for controlled release of pharmaceutically active substances includes, apart from the totality of the capsules of enteric or gastric release which are known in the art, also the microcapsules whose only aim is the simple masking of the taste of the pharmaceutically active substance which they encapsulate until the latter pass through the mouth.

Furthermore, in the present description, the term microspherules and microcapsules is used indiscriminately and alternatively for practicles of dimensions ranging from a few tenths of a micrometer up to 5000 micrometers, preferably up to 1000 micrometers and more preferably up to 500 micrometers. Moreover, the term artistic shape includes all forms that are an artistic model of, for instance, a fruit or an animal or an object, etc., such as for example children's toys.

Only few of the numerous classes of pharmaceutical products that may be converted into microcapsules for controlled release and used for the production of confectionery preparations, in accordance with the present invention, are listed below:

1. Anti-inflammatory substances
2. Factors for dilatation of the coronary artery
3. Tranquillizers
4. Nutrient additives
5. Diuretics
6. Pharmaceuticals against migraine
7. Pharmaceuticals against angina pectoris
8. Expectorants
9. Antipyretics
10. Anti-cholesterinemic and anti-lipidemic agents
11. Anti-arrhythmics
12. Ion-exchange resins
13. Inorganic supplements such as potassium chloride, calcium carbonate, magnesium oxide and other salts of alkaline metals and of alkaline-earth metals
14. Laxatives
15. Vitamins
16. Compounds for the binding of the acids of the stomach
17. Antitussives
18. Antihistaminics
19. Various alkaloids
20. Decongestives

As well as mixtures of microcapsules including chemically interacting incompatible with one another pharmaceuticals such as vitamin C and calcium carbonate or cholestyramine and potassium chloride.

For the better understanding of the present invention, two examples of its execution are given below, which, however, do not limit its scope.

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EXAMPLE 1

Composition of an ice-cream substitute		
Water-proof microcapsules of pharmaceutically active substance	1000 g	
Milk powder FAO/WHO	470 g	
Sacharose USP	1500 g	
Lecithin USP	180 g	
Casein USP	50 g	
Glucose USP	180 g	
Vegetal gum USP	10 g	
Synthetic sweetener USP	adequate amount	
Flavor USP	adequate amount	
Colorant USP	adequate amount	
Water USP sufficient quantity up to	10000 g	

Following complete dissolution of all the above mentioned excipients under stirring and eventual slight warming, they are transferred to the special continuous-operation machine for production of ice cream, in the cream feeding vessel.

The mixture is cooled to a temperature slightly below zero, and, under vigorous stirring, the pharmaceutically active substance is added all at once, starting at the same time the production of the ice cream and its swelling by 100% by means of nitrogen blown from a steel container. The above product is filled into recipients made of composite sheet and the formulated pieces are kept at a temperature of -40° C. with excellent results as regards their preservation.

EXAMPLE 2

Composition of commercial ice-cream		
Water-proof microcapsules of pharmaceutically active substance	1.5 Kg	
Fresh milk	6.4 Kg	
Saccharose	1.6 Kg	
Milk cream	1.6 Kg	
Egg yolks	0.3 Kg	
Glucose	0.15 Kg	
Alpigen Super	0.05 Kg	
Couantreau	0.03 Kg	
half a teaspoonful of vanilla		

Proceed as in case of example 1, with the only difference that the formulated pieces of ice cream are of the well known shape and dimensions of ice cream coated with chocolate that is held by means of a small wooden rod, or of ice-cream that is filled in cups of different sizes.

Note:

In working in accordance with the process indicated in example 1, for the same amount of microcapsules, we used, instead of the aforementioned synthesis of commercial ice-cream, a synthesis of commercial ice-lolly made of fruit juices, with equally satisfactory results.

We claim:

1. A process for preparation of a confectionery formulation for controlled release of a pharmaceutically active substance, said process comprising:

- a) mixing a plurality of coated microcapsules containing said pharmaceutically active substance with a confectionery substance in a liquid phase to form a confectionery mixture, said confectionery substance containing water and being solidifiable into a solid matrix

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which can contain a small amount of water that has not solidified, and

b) cooling the confectionery mixture to a temperature at which the confectionery substance solidifies with addition of a gas under pressure to form the confectionery formulation comprising the coated microcapsules surrounded by a confectionery matrix having a solid phase comprising the solid matrix, a possible liquid phase comprising the unsolidified water and a gas phase comprising the gas, said coated microcapsules comprising a water-proof coating to protect the pharmaceutically active substance from the unsolidified water.

2. A process as claimed in claim 1 wherein the confectionery matrix and the water-proof coating of the coated microcapsules are sufficiently soluble in a mouth of a patient to be treated so that the formulation can melt in the mouth without chewing.

3. A process as claimed in claim 2 wherein the confectionery matrix is ice cream and the water-proof coating has a melting point below about 30° C.

4. A process as claimed in claim 3 wherein the mixing in step a is done at a temperature of between about 0° C. and -1° C.

5. A process as claimed in claim 4 wherein the mixture is cooled to below about -18° C. in step b.

6. A process as claimed in claim 5 wherein the gas is an inert gas.

7. A process as claimed in claim 6 wherein the inert gas is nitrogen which is added in an amount sufficient to swell a volume of the confectionery mixture by about 50%-150%.

8. A process as claimed in claim 3 wherein the process comprises a step of coating the microcapsules with said water-proof coating immediately prior to the mixing in step a.

9. A process as claimed in claim 8 wherein the step of coating said microcapsules comprises spraying the microcapsules with a sufficient quantity of edible vegetal oil to coat the microcapsules, and blowing said sprayed microcapsules with air at a temperature sufficiently low to solidify the oil and to polish the microcapsules.

10. A process as claimed in claim 9 wherein, prior to coating the microcapsules with the water-proof coating, the process comprises polishing the microcapsules with a pharmacologically acceptable hydrophobic substance.

11. A process as claimed in claim 9 wherein the process comprises forming the formulation of step b into a candy and coating said candy with a layer of chocolate, caramel, water or a combination thereof.

12. A process as claimed in claim 11 wherein said candy is provided with score lines so that it can be readily subdivided.

13. A process as claimed in claim 11 wherein the process comprises hermetically sealing the candy in a thin-walled receptacle comprising a composite sheet with layers of paper, plastic, metal or a combination thereof.

14. A process as claimed in claim 5 wherein the process comprises storing the confectionery formulation at a temperature between about -20° C. and -40° C.

15. A confectionery formulation for the controlled release of a pharmaceutically active substance, said formulation comprising

a) an edible binding matrix that is storable at a storage temperature of between about -18° C. and -40° C.; said matrix comprising a solid phase, a liquid phase comprising eutectic water, and a gas phase at said storage

temperature, said edible matrix being soluble in a mouth of a patient; and

b) a plurality of microcapsules embedded in said matrix, each of said microcapsules comprising the pharmaceutically active substance and a coating comprising one or more hydrophobic substance or substances selected from the group consisting of a vegetal oil, a wax and a combination thereof, said hydrophobic substance or substances being present in said coating in an amount sufficient to protect said pharmaceutically active substance from said eutectic water during storage of the formulation at said storage temperature, said coating being soluble in the mouth of the patient.

16. A confectionery formulation as claimed in claim 15 wherein the binding matrix comprises ice cream.

17. A confectionery formulation as claimed in claim 15 wherein the binding matrix comprises ice lolly.

18. A confectionery formulation as claimed in claim 15 wherein the formulation comprises:

Pharmaceutically active substance	0.1-25%
Milk powder/FAO/WHO	1-18%
Saccharose USP	10-18%
Lecithin USP	2-4%
Casein USP	0.5-4%
Glucose USP	2-4%
Vegetal gum USP	0.1-1%
Synthetic sweetener USP	Desired Amount
Flavor USP	Desired Amount
Colorant USP	Desired Amount
Water USP sufficient quantity up to	100%

19. A confectionery formulation as claim 16 wherein the pharmaceutically active substance is a medicinal product selected from the group consisting of:

anti-inflammatory substances, factor for dilatation of the coronary artery, tranquilizers, nutritive additives, diuretics, medicines against migraine, anti-asthmatics, expectorants, antipyretics, anti-cholesterinemic agents, anti-lipidemic agents, anti-arrhythmics, ion-exchange resins, inorganic supplements, laxatives, vitamins, compounds binding the acids of the stomach, antitussives, anti-histaminics, alkaloids, and decongestives, said medicinal product being present in the formulation in an amount of about 0.1-25% by weight.

20. A process for rendering microcapsules comprising a pharmaceutically active substance suitable for inclusion in a confectionery matrix, said matrix being soluble in the mouth of a patient to be treated and being storable at a temperature at which the matrix comprises a solidified substance and eutectic water, said process comprising:

a) coating said microcapsules with a vegetal oil and mixing said coated microcapsules with said confectionery matrix at an initial temperature at which the matrix is in liquid phase whereby to form a mixture; and

b) cooling the mixture to a solidifying temperature at which the matrix comprises the solidified substance and the eutectic water.

21. A process as claimed in claim 20 wherein the process comprises adding nitrogen gas under pressure to the mixture in step a.

22. A process as claimed in claim 20 wherein the confectionery matrix is ice cream, the initial temperature is about -18° C. to -1° C. and the solidifying temperature is about -18° C. or below.

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EUROPEAN PATENT APPLICATION

21 Application number: **93202118.1**

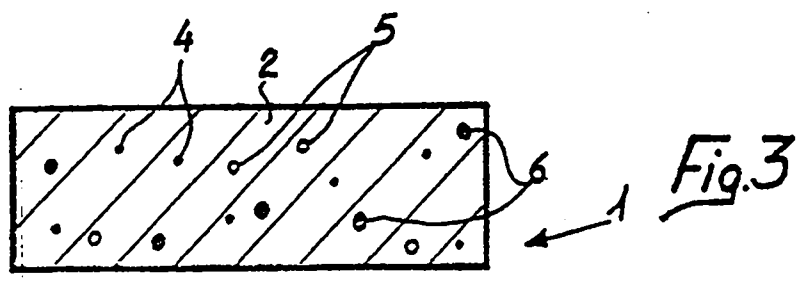
51 Int. Cl.⁵: **A23G 3/00**

22 Date of filing: **20.07.93**

30 Priority: 22.07.92 IT MI921772 43 Date of publication of application: 26.01.94 Bulletin 94/04 84 Designated Contracting States: AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE	71 Applicant: ATP AVANT-GARDE TECHNOLOGIES & PRODUCTS S.A. MARKETING & LICENSING 5, Via Curti CH-6900 Lugano(CH) 72 Inventor: Maggi, Giulio Cesare 11, Viale Regina Giovanna I-20129 Milano(IT) 74 Representative: Riccardi, Sergio Riccardi & Co. Via Macedonio Melloni, 32 I-20129 Milano (IT)
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54 Chewing gum with a varying effect in taste and time.

57 A chewing gum is described which has a varying effect both regarding its taste and regarding the time during which this taste lasts. Said chewing gum (1) is constituted by a gummy mass (2) having inside a plurality of microcapsules (4,5,6) dispersed in it. Each of said microcapsules contains active nutritional, confectionery and/or medicinal substances, such microcapsules being made with materials able to allow the time necessary for releasing the substances contained in them to be predetermined.



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This invention regards a chewing gum with varying effect in time and taste.

Currently numerous ingestable products are known which utilise aromas and, generically, agents which modify taste and odour.

In the particular case of chewing gum the taste-odour is contained in a simple aqueous solution which is immediately released as chewing begins.

This is a disadvantage in that the taste or aroma released remains at very low levels after only a few minutes of chewing, thus quickly losing such particular characteristics and generating disappointment in the consumer who after a short time finds himself chewing a gum with a neutral or even unpleasant taste.

In particular numerous attempts have been made to incorporate pharmaceutical substances in chewing gum, but up till now a chewing gum which releases the active substances incorporated in it in a sustained, controlled and reproducible way has not been able to be obtained given the enormous differences in the ways and forces of mastication which vary from person to person.

The main objective of this invention is that of eliminating the disadvantages stated above in the known types of chewing gum obtaining a chewing gum which allows the intensity of active nutritional, confectionery, and/or medicinal substances contained in them to be kept constant for predetermined times.

Within the scope of the problem described hereinbefore another important objective is that of realising a chewing gum, which adds to the previous characteristics that of releasing in predeterminable temporal succession one or more of said active nutritional, confectionery and/or medicinal products.

Another important objective is that of obtaining a chewing gum which allows the trend of the releasing of said substances to be programmed according to a set temporal curve.

All these problems are particularly serious and difficult when one wishes to incorporate pharmacologically active substances in a chewing gum, obtaining reproducible and reliable performances which are independent of the chewing habits of each person.

Not least is the objective of obtaining a chewing gum which adds to the previous characteristics, that of being pleasant to chew.

The problem and the above mentioned objectives are obtained by a chewing gum with a varying effect in time and taste which is characterised in that it is constituted by a gummy mass with a plurality of microcapsules dispersed in it, said microcapsules containing active alimentary, confectionery and/or medicinal substances and allowing the time necessary for releasing the contents to be predetermined.

Further characteristics and advantages of the invention are shown by the description of particular forms of embodiment given as non-limiting examples, illustrated as an example and not limiting the invention, by the appended sheets of drawings in which:

Figure 1 illustrates a temporal curve of the release of the substances available in a chewing gum of known type;

figure 2 illustrates a perspective view of a chewing gum realised according to the principles of this invention; figure 3 illustrates a sectional view of said gum taken according to a plane of section III-III of figure 2;

figure 4 illustrates a section of an ideal microcapsule;

figures 5 to 7 illustrate temporal curves in relation to particular microcapsules utilised;

With reference to the figures cited hereinbefore, in Figure 1 the usual condition of temporal decline in the quantity of the substance available in the chewing gum of known type is illustrated.

One can thus verify how the highest quantity of the aroma or taste is immediately released from the first chews, the percentage decreasing to very low values after only a few minutes.

Referring to figures 2, 3 and 4 this invention proposes on the other hand realisation of a chewing gum 1, constituted preferably of a gummy mass 2 which has a plurality of microcapsules 3 inside it which in the particular form of embodiment are emphasised in three different groups, indicated with reference numbers 4, 5 and 6.

Each microcapsule 3 has very limited dimensions, generally less than two tenths of a millimetre, and are constituted by an external layer or membrane 7 of material able to allow it to remain whole in the chewing phase for predetermined times.

On the inside of each microcapsule 3 a core of active substance 8 is present, which may be of nutritional, confectionery and/or medicinal type.

The materials constituting the external layer 7 may be, for example, gelatine, cellulose derivatives, polyvinylpyrrolidone, starch, sucrose, lactose and others in various combinations, as is well known in the techniques of microencapsulation of active substances.

In figure 5 a particular utilisation of the invention is illustrated: it refers to the utilisation of groups of microcapsules containing for example, the same substance 8, which is released in the range of different groups, in successive times and in order to allow availability of the desired substance for the required time

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which, theoretically, may be indefinite. The variation of release times may be obtained for example by means of membranes 7 of different nature and/or thickness.

In figure 6 a second possible utilisation of the invention is illustrated: in this groups 4, 5, and 6 of microcapsules containing different active substances 8 are considered, the times for the disgregation of the layer 7 remaining unchanged.

During chewing it may therefore be set for a first period 9 of a given substance, for a second period 10 of a different substance for organoleptic or chemical characteristics and so on for a third period 11. Also here, the succession of release time of the substances contained in various groups of microcapsules, may be obtained by means of known technology in the microencapsulation sector.

In figure 7 a further utilisation of the invention is illustrated in which various groups of microcapsules contain the same type of active substance 8, which however is present in increasing quantities, the external layer or membrane 7 allowing the substance to be available according to predeterminable times by varying its composition and/or thickness.

One may thus for example arrange for a first period 12 of a given quantity of substance for a set time, a greater quantity in a second period 13, again for a predeterminable time, and lastly in a subsequent period 14 for a further increase of available quantity again for a predeterminable time.

It can therefore be seen how the invention has reached the established aim and objectives, it being possible to predetermine the quantity of active substance available during chewing both with regard to its quantity and its duration with respect to time.

As an example, this active substance may be constituted either by a element for modifying taste or aroma, or by a pharmaceutical substance for example for oral hygiene treatment and for bringing flouride to the dental apparatus. Naturally one may use as the active substance any pharmaceutically active substance which can be administered orally, and in particular those pharmaceutical substances and/or medicines which it has already been attempted to include in chewing gum of a conventional type, such as for example dimenhydrinate, paracetamol, vitamin C, cimetidine, sucralphate, D-metofane, ginseng and so on.

It has also been demonstrated how the possibility has been achieved of obtaining, for example, a taste which is constant for even prolonged chewing times or a taste which increases in intensity with time or again the possibility of arranging for different tastes for successive chewing times.

The size of the microcapsules are such as not to be noticed by the tongue during chewing thus avoiding any unpleasant sensation during the same.

Another noteworthy advantage of this invention is that this chewing gum can be made at cold temperatures, directly pressing the formula in the relevant moulds, using simple equipment already used normally for such production, and thus without any necessity for employing special methods or machinery.

Practical experiments have been carried out of incorporation in the chewing gum of two pharmaceutical substances which are particularly interesting for administration in this galenic form, that is dimenhydrinate and vitamin C. The results are reported in the following examples which must however be considered as purely illustrative and not limiting the scope of the invention.

Preliminarily to the in vivo experiments, analyses were carried out of the release in vitro of the chewing gum containing respectively dimenhydrinate and vitamin C, subsequently administered to volunteers taking part in the experiments, obtaining the following results.

DIMENHYDRINATE 25 mg			
	Tablets Lot P/002	Tablets Lot P/003	Tablets Lot 100/ME
Release time	% release	% release	% release
3 min.	75.97 %	66.55 %	37.30 %
6	84.54 %	74.47 %	43.70 %
10	87.39 %	79.15 %	48.30 %
15	88.93 %	79.15 %	51.80 %
25	88.93 %	84.91 %	54.70 %
30	89.15 %	87.43 %	55.85 %

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Claims

1. Chewing gum with varying effect in taste and time, characterized in that it is constituted by a gummy mass with a plurality of microcapsules containing active nutritional, confectionery and/or medicinal substances dispersed in it, said microcapsules allowing the time necessary for releasing their contents to be predetermined.
2. Chewing gum according to claim 1, characterised in that the microcapsules have an external layer realised with materials able to maintain its integrity in the chewing phase for a predeterminable time.
3. Chewing gum according to claims 1 and 2, characterised in that the microcapsules have a core of active substances inside them which are utilised in food sector, the confectionery sector or the pharmaceutical sector, said substances being present in predeterminable quantities and/or having different organoleptic characteristics.
4. Chewing gum according to the preceding claims characterised in that inside the gummy mass is one or more groups of microcapsules having different external layers and/or different active substances inside, the latter in a predeterminable quantity.
5. Chewing gum according to the preceding claims, characterized in that the external layer of the microcapsules is preferably constituted by gelatine and/or cellulose derivatives and/or polyvinylpyrrolidone and/or starch and/or sucrose and/or lactose in various combinations, the thickness of the external layer being variable according to the desired duration of the time in which the layer must remain whole before beginning to release the active substance contained in the microcapsule.
6. Chewing gum according to the preceding claims, characterized in that the microcapsules have dimensions preferably less than two tenths of a millimetre.
7. Chewing gum according to one or more of the preceding claims, characterised in that the microencapsulated active substance is a sustained release pharmaceutically active substance.
8. Chewing gum according to claim 7, characterised in that the pharmaceutically active substance is dimenhydrinate.
9. Chewing gum according to claim 8, characterised in that the dimenhydrinate is incorporated in doses of 25 mg of active substance for each chewable tablet.
10. Chewing gum according to claim 7, characterised in that the pharmaceutically active substance is vitamin C in doses of 250 - 500 mg per chewable tablet.

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES**

202085 19 de Julio de 2007
Bogotá, D.C.,

Abogado
ALICIA LLOREDA
(Apoderado)

ASUNTO	Radicación	02117313
	Trámite	002
	Evento	001
	Actuación	430
	Oficio .. 000	8952
	Folios	8

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

- 1.1. Capitulo descriptivo: folios 18 al 26 como se radicó inicialmente
- 1.2. Capitulo reivindicatorio: folios 27 al 31 como se radicó inicialmente
- 1.3. Prioridad: folio 1, GB 0016173.7 de 30-06-2000

2. Objeto de la invención

Título de la solicitud: Productos de confitería que contienen ingredientes activos.
Folio 1.

Objeto de la invención: El objeto de la presente solicitud de patente de invención consiste en un producto de confitería, por ejemplo chocolate, que contiene uno ó más ingredientes activos, caracterizado porque los ingredientes activos están incorporados en una pluralidad de cuerpos transportadores dispersos dentro del cuerpo del producto de confitería.

El objeto de la solicitud definido anteriormente se clasificó en la IPC A23G 3/00.

3. De la solicitud de Patente (artículo 28 y 30 D. 486)

El título de la solicitud en estudio "Productos de confitería que contienen ingredientes activos" no es claro puesto que no refleja el objeto de la invención ni el campo industrial específico al cual esta aplicado. De acuerdo con el artículo 6 del decreto 2591 de 2000.

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Conforme a la legislación y de acuerdo con el capítulo descriptivo y el capítulo reivindicatorio estudiados, se observa que:

En la reivindicación 1 se hace referencia a un producto de confitería en donde los ingredientes activos van incorporados en una pluralidad de cuerpos portadores dispersos en el cuerpo del producto, pero es muy amplia y ambigua y no define la materia de la invención.

La reivindicación 2 es muy amplia y no define la materia que se desea proteger porque enumera una serie de elementos demasiado disímiles que no tienen una clara orientación técnica. Además no se encuentra sustento en la descripción, pues solo se menciona un único ejemplo que no involucra todos los elementos mencionados. Lo mismo ocurre con las reivindicaciones 5, 6, 7, 8, 9, 10 y 11.

Las reivindicaciones 20 y 21 son dependientes de la reivindicación 11 que hace referencia a la bacteria microbiana del producto de confitería y por lo tanto no hay ninguna correspondencia entre ellas.

Las reivindicaciones 22 a 26 son muy amplias y no delimitan el objeto de la invención puesto que los cuerpos portadores se caracterizan con intervalos muy amplios por ejemplo "...en donde los cuerpos portadores poseen un volumen situado entre 0,125 y 8000...", "...contiene desde 0,000001 hasta 100% en peso del ingrediente activo", "...desde 0,000001 hasta 50%...", "...entre 0,1% y 99%..." y "...va desde 1 hasta 10000", dando lugar a una gran falta de concisión.

La reivindicación 28 y 29 plantea un proceso para la preparación de un producto de confitería, el cual no está definido en etapas ni condiciones específicas para su realización. Y en cambio menciona el objetivo a alcanzar, tal y como se lee en la enunciado "...a fin de asegurar que la estructura de los cuerpo portadores permanezca intacta..."

En conclusión, estas reivindicaciones no cumplen con el requisito de claridad y concisión o sustento por la descripción de acuerdo al art. 30 de la Decisión 486.

4. Determinación del Estado de la Técnica

Considerando que la fecha de prioridad de la solicitud internacional PCT es 30/06/2000, se encontraron documentos del estado de la técnica relacionados, con una fecha de publicación anterior a esta.

Se encontró como anterioridades los documentos relacionados a continuación, que pueden afectar la patentabilidad del objeto de la presente solicitud:

N°	DOCUMENTO	TÍTULO	FECHA DE PUBLICACIÓN
D1	US5525352	Confectionery delivery system for pharmaceutically active substances.	1996-05-11
D2	EP0580240	Chewing gum with a varying effect in taste and time	1994-01-26

Se anexa las páginas relevantes de cada documento al expediente.

5. Evaluación de los requisitos de patentabilidad (artículo 14 D486)

En cumplimiento del artículo 14 de la Decisión 486, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

5.1. Novedad (artículo 16 D486)

La presente Solicitud de Patente Colombiana No. 02117313 en su reivindicación 1, presenta un producto de confitería básico que contiene uno ó más ingredientes activos, caracterizado porque los ingredientes activos van incorporados en una pluralidad de cuerpos portadores dispersos en el cuerpo del producto de confitería.

La anterioridad D1 presenta una matriz de confitería que contiene microcápsulas para liberación controlada de ingredientes activos (columna 5 renglón 17 – 67).

El tamaño de partícula de dichas microcápsulas puede estar entre 5000µm ó menos y los ingredientes activos contenidos en estas son sustancias farmacológicamente activas como vitaminas, minerales, antioxidantes, entre otros.

Entonces, la reivindicación 1 de la solicitud en estudio no es nueva y las reivindicaciones dependientes de esta tampoco lo son, puesto que ingredientes activos formulados en cuerpos portadores, como microcápsulas ó microesferas, ya habían sido presentados en D1, además tales microcápsulas se encuentran dispersas en un cuerpo de un producto de confitería.

La anterioridad D2 presenta un producto de confitería (goma de mascar) que contiene una pluralidad de microcápsulas dispersas en el cuerpo del producto. Dichas microcápsulas contienen activos nutricionales, confitería y/o sustancias medicinales. Por lo tanto la reivindicación 1 de la solicitud en estudio no es nueva, puesto que plantea los mismos elementos esenciales presentados en la anterioridad D2.

Las reivindicaciones 28 y 29 hacen referencia a un proceso para la preparación de un producto de confitería de acuerdo con la reivindicación 1 que consiste en agregar los cuerpos portadores al componente de confitería en forma líquida y luego solidificarlo. Este proceso ya se había divulgado previamente en la anterioridad D1 (columna 6 renglón 22-32), donde se mezclan las microcápsulas con una matriz de confitería fundida y luego se lleva a cabo un proceso de solidificación. Por lo tanto el proceso de las reivindicaciones 28 y 29 no es nuevo.

6. Conclusión:

La solicitud presenta problemas de claridad (*artículos 28 y 30*). Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	DOCUMENTO	REIVINDICACIONES AFECTADAS	REQUISITO QUE AFECTA
D1	US5525352	1-29	Novedad
D2	EP0580240	1-29	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación. **En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.**

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha **27 JUL. 2007**

27 JUL. 2007

CONCEPTO TECNICO No. 988	EXAMINADOR TECNICO Código No.202085
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